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10/590,311

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

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1623

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Application No. 10/590,311-Advisory Action: Box 11-Attachment**

The After Final Amendment is not entered.

**Box 3(a):** New claims 26-27 are drawn to prophylaxis, which have enablement issues.

**Box 3(c)/Box 7:** Regarding the rejection of Claims 1-17 and 19-25 under 35 USC 103 applicants argue that:

1. Komai does not teach the effect of gellan sulfate on the IL-1 mediated degradation of cartilage as disclosed in Hill and the treatment of osteoarthritis.
2. Osteoarthritis and rheumatoid arthritis are two different illnesses according to Dictionary.com, Bioiberica's Medical Report and Martindale-The extra Pharmacopeia. Inflammation in osteoarthritis generally only plays a minor role whereas rheumatoid arthritis is characterized principally synovial inflammation.
3. Hill does not exemplify treatment of osteoarthritis and does not teach treatment via oral administration.

Applicants' arguments are not found to be persuasive.

Hill et al, drawn to antiinflammatory compounds, teach that polysulfated polysaccharides like alginate acid, pectin and inulin have a variety of biological activities including antiinflammatory activity and are useful for treatment of osteoarthritis via direct injection into the synovial cavity of an arthritic joint. The said sulfated polysaccharides can also be used as their salts. Hill may not have exemplified his teaching or suggested oral administration. But his teaching does point out to the use of the said polysaccharides for osteoarthritis. Oral administration of an active agent in a method of treatment is well known to one of ordinary skill in the art.

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Komai et al teach the use of gellan sulfate which acts as a ligand for extra domain A containing fibronectin, which is found to be in high concentration in patients with rheumatoid arthritis, can have a therapeutic effect (abstract). According to the definitions in Dictionary.com and the Affidavits Martindale and Osteoarthritis and Cartilage (1999) both rheumatoid and osteoarthritis involve degradation of bone joints, synovial inflammation and cartilage erosion/destruction. Since Hill teaches the use of polysulfated polysaccharides for osteoarthritis and both rheumatoid and osteoarthritis involve degradation of bone joints, synovial inflammation and cartilage erosion/destruction one of ordinary skill in the art will use the active agents including gellan sulfate, as instantly claimed for treatment of osteoarthritis. The Declaration of Ana Maria Gibert just shows that a higher dosage (80 mg/Kg/) of inulin polysulfate showed significant improvement. The result shown in the Declaration is an optimization of the dosage for obtaining maximum beneficial effects using the active agent that Hill teaches for the same purpose. Such optimization is routine in the art and will also be carried out by one of ordinary skill in the art. The instant invention is rendered obvious by the prior art.

**Box 5:** The After Final Amendment would have overcome the rejections under 35 USC 112, first and second paragraphs of record if it had been entered.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

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Supervisory Patent Examiner, Art Unit 1623